

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DAT | TE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---------------------|------------------------------|-----------------|----------------------|---------------------|-----------------|
| 10/673,629 | 09/29/2003 | | Hector F. DeLuca | 1256-00923 | 2546 |
| 26753 | 7590 11/ | 30/2004 | | EXAMINER | |
| | SCEALES, STA | HUI, SAN MING R | | | |
| | ISCONSIN AVE EE, WI 53202 | INUE, SUITE | ART UNIT | PAPER NUMBER | |
| WILLWHOLEE, WI 2222 | | | | 1617 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| · | | <u> </u> | | | | |
|---|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 10/673,629 | DELUCA ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | San-ming Hui | 1617 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | <u>_</u> . | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | _ · · | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 18-22 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) 18-22 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example. | epted or b) objected to by the Idrawing(s) be held in abeyance. See iion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | • | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal P 6) Other: | atent Application (PTO-152) | | | | |

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

Ē

Art Unit: 1617

DETAILED ACTION

The application is a divisional application of 09/616,164.

Applicant's amendments filed September 7, 2004 have been entered.

Claims 18-22 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al (US Patent 5,843,928).

Deluca et al. teaches a genus of vitamin D compounds including 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D₃, an exemplified compound, as useful in treating leukemia, colon cancer, breast cancer and prostate cancer (See claim 32, also col. 4, lines 43-47). Deluca et al. also teaches the vitamin D compounds therein, in a dosage of 0.01 to 100mcg/day as useful in treating leukemia, colon cancer, breast cancer and prostate cancer (See col. 4, lines 43-52).

Deluca et al. does not specifically teach 2-methylene-19-nor-20(S)- 1α ,25-dihydroxyvitamin D₃ as useful in treating leukemia, colon cancer, breast cancer and prostate cancer.

phoduoti com critamise.

Art Unit: 1617

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-methylene-19-nor-20(S)-1 α ,25-dihydroxyvitamin D₃, in the herein claimed dosage, in a method of treating leukemia, colon cancer, breast cancer and prostate cancer.

One of ordinary skill in the art would have been motivated to employ 2-methylene-19-nor-20(S)-1 α ,25-dihydroxyvitamin D₃, in the herein claimed dosage, in a method of treating leukemia, colon cancer, breast cancer and prostate cancer. It is known that the vitamin D compounds of Deluca as useful to treat leukemia, colon cancer, breast cancer and prostate cancer. Possessing teachings of Deluca et al., one of skilled artisan would have motivated to employ any of the vitamin D compounds of Deluca et al., including 2-methylene-19-nor-20(S)-1 α ,25-dihydroxyvitamin D₃, in the method of treating leukemia, colon cancer, breast cancer and prostate cancer.

Response to Arguments

Applicant's arguments filed September 7, 2004 averring the teachings of Plum et al. may obviate the outstanding rejections have been considered, but are not found persuasive. Examiner notes that Plum et al. is published after the effective filing date of the instant application. A post-filing date publication cannot be a probative evidence for non-obviousness because unobviousness has to be established at the time the invention was made. Therefore, the arguments are considered moot. The rejection set forth in the previous office action remains.

Art Unit: 1617

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui Primary Examiner Art Unit 1617